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No. 80-1607

In the Supreme Court of the United States

OCTOBER TERM, 1980

ALCON LABORATORIES (PUERTO RICO), INC., ET AL.,
PETITIONERS

v.

UNITED STATES OF AMERICA

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FIRST CIRCUIT

BRIEF FOR THE UNITED STATES IN OPPOSITION

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QUESTIONS PRESENTED

1. Whether a district court may enjoin the government from bringing any seizure or injunction action with regard to the illegal marketing of an alleged unapproved "new drug" pending an agency hearing ordered by the court into the "new drug" status of the product.

2. Whether, in an action to seize illegally marketed "new drugs," the district court erred in remanding the new drug issue to the FDA.

3. Whether 28 U.S.C. 2105 barred the court of appeals from reviewing the orders of the district court enjoining agency enforcement, dissolving the seizure of misbranded drugs, and remanding the "new drug" issues to the FDA.

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OPINIONS BELOW

The opinion of the court of appeals (Pet. App. 1a-23a) is not yet reported. The opinion and order of the district court (Pet. App. 27a-33a) is not reported.

JURISDICTION

The judgment of the court of appeals (Pet. App. 24a) was entered on February 24, 1981. The petition for a writ of certiorari was filed on March 23, 1981. The jurisdiction of this Court is invoked under 28 U.S.C. 1254(1).

STATEMENT

1. Alcon Laboratories makes drug suppositories called WANS No. 1, WANS No. 2, and WANS Children Anti Nausea Supprettes ("WANS"), which it sells for use in the symptomatic treatment of nausea and vomiting. The drugs' active ingredients are pyrilamine maleate (an antihistamine) and pentobarbital sodium (a barbiturate). The Food and Drug Administration ("FDA") has never approved the marketing of these ingredients or any similar combination drug for the treatment of nausea and vomiting (Pet. App. 1a-2a).

On March 17, 1978, FDA informed Alcon and other drug companies that the agency's Neurological Drugs Advisory Committee had reported that children treated for nausea with drugs containing pyrilamine maleate and pentobarbital had experienced severe and sometimes fatal reactions.[1] The agency further stated that there is no evidence of the safety and efficacy of pyrilamine maleate with or without a barbiturate in the treatment of nausea and vomiting. It advised Alcon and all other known manufacturers of fixed-combination pyrilamine maleate pentobarbital sodium antiemetic suppositories that these drugs are unapproved new drugs[2] being marketed in violation

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[1] Although petitioners have argued that FDA did not in fact have reports of fatal reactions, they do not dispute that there are reports of severe reactions to the drugs.

[2] Section 201(p) of the Federal Food, Drug, and Cosmetic Act defines a "new drug" as a drug not generally recognized by qualified experts as safe and effective for its intended use. 21 U.S.C. 321(p). It is illegal to market a new drug unless the FDA has approved a new drug application ("NDA") for it. See Section 505 of the Act, 21 U.S.C. 355; *Weinberger* v. *Hynson, Westcott & Dunning, Inc.*, 412 U.S. 609 (1973).

of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 301 *et seq.*, and that, unless they stopped manufacturing the drugs, FDA would initiate legal action under the seizure and/or injunction provisions of the Act. All manufacturers except Alcon acceded to the FDA's request to cease the manufacture and interstate distribution of these drugs (Pet. App. 3a-4a).

On April 3, 1978, Alcon responded that while FDA had never approved the drug, WANS needed no regulatory approval because it was generally recognized as safe and effective by experts and thus was not a "new drug" within the meaning of Section 201(p) of the Act, 21 U.S.C. 321(p). Alcon submitted to the FDA published and unpublished reports purporting to establish the safety and efficacy of WANS. Although Alcon refused to discontinue marketing WANS, it suggested that it would relabel the product in light of an FDA Report that WANS may be unsafe when administered to children under the conditions of use recommended in WANS labeling. After reviewing these submissions, the FDA concluded that Alcon had not produced satisfactory evidence to support the safety and efficacy of WANS, and that WANS could not be brought into compliance with the Act merely by relabeling the product (Pet. App. 4a-5a).

2. On September 21, 1978, the United States filed a complaint for forfeiture in the United States District Court for the District of Puerto Rico against all lots of WANS products in petitioners' possession. The complaint alleged that the products are misbranded within the meaning of Section 502(f)(1) of the Act, 21 U.S.C. 352(f)(1), since they are "new drugs" which have not been approved for marketing. Shortly thereafter, the United States Marshal seized approximately 454,000 WANS suppositories. Peti-

tioners admitted that the drugs did not have regulatory approval but argued that no such approval was necessary because the drugs are not "new drugs" within the meaning of the Act. Because petitioners continued to make and distribute WANS, two months later the United States sought an injunction barring petitioners from distributing WANS until the FDA issues an approved new drug application covering that drug.[3] The district court denied a request for a temporary restraining order and deferred ruling on the requests for a preliminary and permanent injunction (Pet. App. 5a).

The district court consolidated the seizure and injunction actions, gave the parties 90 days to complete discovery, and set trial for May 7, 1979 (Pet. App. 5a). On March 21, 1979, however, petitioners moved to continue the trial date, and to remand the case to the FDA "with instructions to defer regulatory action against * * * WANS * * * or against defendants based upon the alleged 'new drug' status of WANS until FDA makes an administrative determination of the new drug status of WANS in conformity with the enforcement priorities enunciated in FDA's Compliance Policy Guide 7132c.08" (Pet. App. 6a). On April 19, 1979, the court rescinded the scheduled trial date without setting a new date. The government opposed the motion for remand and promptly asked the court to reinstate the trial date or to schedule a prompt hearing on its request for a preliminary injunction. More than eight months later, while the government's motions were

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[3] Section 301(d) and (*l*) prohibits the introduction into interstate commerce of unapproved new drugs, or the doing of any act which results in the misbranding of a drug held for sale after shipment in interstate commerce. 21 U.S.C. 331(d) and (*l*). Section 302 authorizes injunctive actions to prevent violations of Section 301. 21 U.S.C. 332.

still pending, the United States filed a second seizure action against WANS in the district court.

3. On February 27, 1980, the court issued, without opinion, an order (1) consolidating the two seizure actions and the injunction action; (2) remanding the proceedings to the FDA to hold a hearing pursuant to 5 U.S.C. 554 on the "new drug" status of WANS; (3) enjoining FDA from taking enforcement action against WANS or petitioners pending "an administrative determination of the new drug status [of] WANS in conformity with the enforcement priorities enunciated in FDA's Compliance Policy Guide 7132c.08," and (4) rendering the prior seizures "without effect" (Pet. App. 25a-26a).

On April 9, 1980, the district court issued an opinion and order to accompany the order of February 27 (Pet. App. 27a-33a). Addressing only the decision to remand the new drug issue to FDA (*id.* at 31a-32a), the court held that the evidence concerning WANS' new drug status was not conclusive, and that this complex and technical question should be remanded to FDA for its initial determination (*id.* at 30a-31a). The district court did not explain why it dissolved the seizures, failed to act on the government's request for an injunction, or enjoined further FDA enforcement.

4. On the government's appeal of both the February and April orders, the court of appeals consolidated the appeals, vacated the district court's orders, and remanded the case for trial (Pet. App. 1a-23a). Relying on *Ewing* v. *Mytinger & Casselberry, Inc.*, 339 U.S. 594 (1950), the court of appeals determined that the district court was without authority to enjoin the government from filing seizure or injunctive actions against WANS and petitioners (Pet. App. 7a-9a).

In addition, the court of appeals ruled that the district court had improperly dissolved the WANS seizures without first determining the "new drug" issue (*id.* at 10a-12a). The court of appeals further concluded that the FDA had not violated its internal enforcement guidelines by seeking enforcement in this case before holding a formal administrative hearing on the new drug issue (*id.* at 17a-20a). Finally, the court of appeals held that the district court had jurisdiction to make a "new drug" determination, and that the doctrine of primary jurisdiction was inapplicable here because the agency itself had initiated enforcement proceedings in the district court in accordance with the Act and because a remand to the agency would only delay the adjudication of the "new drug" status of WANS (*id.* at 17a-23a).[4]

ARGUMENT

The court of appeals' decision is correct and is consistent with the uniform decisions of this Court and of the courts of appeals. Further review of this interlocutory decision is plainly unwarranted.

1. The court of appeals correctly held that the district court lacked authority to enjoin the government from filing seizure or other enforcement actions against WANS pending a court-ordered remand to the FDA. As this Court explained in *Ewing* v. *Mytinger & Casselberry, Inc.*, 339 U.S. 594, 601 (1950),

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[4] The court also found (Pet. App. 8a, 10a, 12a-14a) that the government could appeal the district court's preliminary injunction under 28 U.S.C. 1292(a)(1), and could appeal the district court's order dissolving the seizures and remanding the case to the agency under the collateral order doctrine. See *Cohen* v. *Beneficial Industrial Loan Corp.*, 337 U.S. 541 (1949); *Swift & Co. Packers* v. *Compania Colombiana Del Caribe*, 339 U.S. 684 (1950).

a district court cannot "step in, stay the institution of seizures, and bring the administrative regulation to a halt until it hears the case." The *Ewing* decision, which is the cornerstone of public health protection, reflects congressional intent to permit the FDA to initiate seizure and injunctive actions pending prompt judicial review of the dispute, thereby keeping potentially dangerous or ineffective drugs out of the public's hands. And this Court and the courts of appeals have repeatedly and uniformly endorsed the prophylactic *Ewing* rule. See, *e.g.*, *Calero-Toledo* v. *Pearson Yacht Leasing Co.*, 416 U.S. 663, 679 (1974); *Fuentes* v. *Shevin*, 407 U.S. 67, 92 & n.27 (1972); *Abbott Laboratories* v. *Gardner*, 387 U.S. 136, 147-148 (1967); *Premo Pharmaceutical Laboratories, Inc.* v. *United States*, 629 F.2d 795, 301 (2d Cir. 1980); *Southeastern Minerals, Inc.* v. *Harris*, 622 F.2d 758, 763-765 (5th Cir. 1980); *Pharmadyne Laboratories, Inc.* v. *Kennedy*, 596 F.2d 568, 569-571 (3d Cir. 1979); *Parke, Davis & Co.* v. *Califano*, 564 F.2d 1200 (6th Cir. 1977), cert. denied, 435 U.S. 942 (1978); *Natick Paperboard Corp.* v. *Weinberger*, 498 F.2d 125, 127 (1st Cir. 1974).

Without citing any authority, petitioners erroneously suggest (Pet. 18-19 & n.14) that *Ewing* is applicable solely to seizure cases involving misbranded drugs, and is not controlling with regard to the seizure of "new drugs."[5] But the seizure of WANS

[5] Petitioners also contend (Pet. 19-20) that *Ewing* is distinguishable because the seizure actions in this case violated FDA's own internal guidelines, and are "without factual or legal justification." But the district court enjoined enforcement proceedings without first addressing those "factual or legal" issues. Nor did the district court find that the FDA had violated its regulations or otherwise acted in an improper manner. To the contrary, the court of appeals properly deter-

was based on charges of misbranding, since an unapproved new drug is a misbranded drug. Moreover, *Ewing* involved the same statutory provision that authorizes the seizures challenged here (21 U.S.C. 334) and that decision unquestionably governs the "regular operation of the seizure procedures established by the Act" (*Abbott Laboratories* v. *Gardner*, *supra*, 387 U.S. at 148), including the "new drug" seizure in this case. Accord, *Premo Pharmaceutical Laboratories, Inc.* v. *United States*, *supra* (new drug seizures); *Southeastern Minerals, Inc.* v. *Harris*, *supra* (seizure of unapproved new animal feed); *Pharmadyne Laboratories, Inc.* v. *Kennedy*, *supra* (new drug seizures); *Parke, Davis & Co.* v. *Califano*, *supra* (new drug seizures); *Natick Paperboard Corp.* v. *Weinberger*, *supra* (adulterated food). Petitioners' narrow construction of the *Ewing* doctrine would breach the broad public protection established by Congress and repeatedly enforced by the courts.[6]

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mined that the guidelines cited by petitioners are simply inapplicable to WANS (Pet. App. 17a-20a). We further note that the *Ewing* rule is controlling even where the FDA has improperly instituted an enforcement action. In *Ewing* itself, for example, the trial court had found that the multiple seizures were purposefully designed to harass the drug manufacturer and were an abuse of discretion (339 U.S. at 604 (Jackson, J., dissenting)). See also *Pharmadyne Laboratories, Inc.* v. *Kennedy*, *supra*, 596 F.2d at 571 n.6.

[6] Likewise, it is irrelevant that the district court enjoined only seizures "based upon a 'new drug' charge," while permitting FDA to seize WANS if it could show that the drug is " 'unsafe' or 'dangerous to health' " (Pet. 19 & n.15). In *Ewing*, the Court assumed that the drug was "not dangerous to health" and "relatively innocuous" (339 U.S. at 601). The Court nonetheless held that "the statutory scheme treats every 'misbranded article' the same in this respect" and it empha-

Petitioners' reliance (Pet. 20-21) on *Weinberger* v. *Bentex Pharmaceuticals, Inc.*, 412 U.S. 645 (1973), is misplaced. The *Bentex* opinion does not refer to the *Ewing* decision, which has subsequently been cited by this Court with approval (*Calero-Toledo* v. *Pearson Yacht Leasing Co.*, *supra*, 416 U.S. at 679), much less purport to overrule or restrict the *Ewing* doctrine. Rather, *Bentex* concerned a suit by several drug manufacturers for a declaratory judgment regarding the status of their drug. *At the FDA's request*, the district court remanded the case to the agency to allow it to make the "new drug" determination in the first instance. With the FDA's acquiescence, the district court enjoined all enforcement actions against the drug manufacturers in the interim. See *Bentex Pharmaceuticals, Inc.* v. *Richardson*, 463 F.2d 363, 369 (4th Cir. 1972). Thus, the only question before the Court in *Bentex* was whether the district court had authority in a declaratory judgment action to remand the new drug issue to the FDA at its request. In upholding the FDA's right to exercise primary jurisdiction in the circumstances of that case, the Court did not suggest that the district court may enjoin and remand an FDA enforcement action over the agency's objection.[7]

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sized that its decision "determines the jurisdiction of the District Court in all the cases in that category" (*ibid.*).

[7] *Rutherford* v. *United States*, 542 F.2d 1137 (10th Cir. 1976), is also readily distinguishable. In that unique case, a terminally-ill cancer patient sought a declaration that laetrile is not a new drug and an injunction precluding the agency from interfering with his personal supply of laetrile pending a determination of the drug's status by the agency. See *id.* at 1144 (McWilliams, J., dissenting). The court of appeals did not enjoin FDA enforcement actions against the drug distributors or against the drug generally. Furthermore, the

2. For similar reasons, the court of appeals correctly held (Pet. App. 21a) that the district court had improperly invoked the doctrine of primary jurisdiction in this case. At the outset, we note that a remand would be purposeless for petitioners unless it is coupled with an injunction against interim agency enforcement. Indeed, petitioners acknowledged in the court of appeals that "[a] remand in the absence of administrative restraint is simply meaningless" (Motion for Reconsideration, at 4). Because *Ewing* precludes the courts from enjoining or interfering with agency enforcement actions, a remand order would simply waste both petitioners' and the FDA's time and resources. In short, the court of appeals cannot be faulted for declining to uphold that portion of the district court's order that does not serve petitioners' ends.

At all events, petitioners' primary jurisdiction argument is wholly without merit. Since 1938 the government has brought hundreds of enforcement actions under Section 505 against unapproved new drugs. With the exception of the district court's order in this case, we are aware of no district court decision remanding an enforcement action to the agency for a new drug determination. In fact, in those few cases where defendants have sought to have the issue referred to the agency, the courts have uniformly refused to apply the primary jurisdiction doctrine. See, *e.g.*, *United States* v. *X-Otag Plus Tablets*, 602 F.2d

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Tenth Circuit has subsequently limited the *Rutherford* decision to its facts and reaffirmed that the district court should not remand a case to the agency where, as here, the FDA has initiated an enforcement action in district court. *United States* v. *X-Otag Plus Tablets*, 602 F.2d 1387, 1390-1391 (10th Cir. 1979).

1387 (10th Cir. 1979); *United States* v. *Mosinee Research Corp.*, 583 F.2d 930 (7th Cir. 1978). As the Second Circuit has explained, "when the agency chooses to go to the district court for enforcement, it makes little sense to refer the very question at issue to the agency." *CAB* v. *Aeromatic Travel Corp.*, 489 F.2d 251, 254 (1974). See also *ICC* v. *B&T Transportation Co.*, 613 F.2d 1182, 1187 (1st Cir. 1980); *Mississippi Power & Light Co.* v. *United Gas Pipe Line Co.*, 532 F.2d 412 (5th Cir. 1976), cert. denied, 429 U.S. 1094 (1977); *ICC* v. *All-American, Inc.*, 505 F.2d 1360, 1362 (7th Cir. 1974). Indeed, the deference for agency expertise and discretion in enforcement tactics that underlies both *Bentex* and *CIBA Corp.* v. *Weinberger*, 412 U.S. 640 (1973) (as well as *Ewing*) strongly supports the conclusion of the court of appeals in this case: where, as here, the agency believes that a drug is misbranded and may be unsafe or ineffective, Congress provided that the FDA could seek enforcement and determination of the new drug issue in district court.

3. Petitioners also erroneously claim (Pet. 23-26) that 28 U.S.C. 2105 barred court of appeals review in this case. That statute, which has generally been ignored or construed narrowly (see, *e.g.*, C. Wright, A. Miller & E. Cooper, *Federal Practice and Procedure* § 3903, at 414-415 (1976); *McGough* v. *First Arlington National Bank*, 519 F.2d 552, 554 (7th Cir. 1975)), applies only to "matters in abatement which do not involve jurisdiction." 28 U.S.C. 2105. Both the *Ewing* doctrine and the concept of primary jurisdiction involve jurisdictional matters, however (see 339 U.S. at 601; *Southeastern Minerals, Inc.* v. *Harris*, *supra*, 622 F.2d at 764 n.10), and thus do not fall

within the limited scope of Section 2105. See *Snyder* v. *Buck*, 340 U.S. 15, 22 (1950); C. Wright, A. Miller & E. Cooper, *supra*, at 413-414. See also *Weinberger* v. *Bentex Pharmaceuticals, Inc.*, *supra*; *Nader* v. *Allegheny Airlines, Inc.*, 426 U.S. 290 (1976) (involving appellate review of orders remanding a case to an agency under primary jurisdiction rationale). In addition, the district court retained jurisdiction over this case pending remand and therefore did not abate the case. See C. Wright, A. Miller & E. Cooper, *supra*, at 414.

CONCLUSION

The petition for a writ of certiorari should be denied.

Respectfully submitted.

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